DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

IMPAC Medical Systems, Inc.
% Kathryn Stinson
Regulatory Affairs Specialist
100 Mathilda Place, 5th Floor
SUNNYVALE, CA 94086

September 5, 2014

Re: k141572
Trade/Device Name: MOSAIQ Oncology Information System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: June 12, 2014
Received: June 18, 2014

Dear Ms. Stinson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K141572

Device Name: MOSAIQ Oncology Information System

Indications For Use:

MOSAIQ® is an oncology information system used to manage workflows for treatment planning and delivery. It supports information flow among healthcare facility personnel and can be used wherever radiotherapy and/or chemotherapy are prescribed.

Users can configure MOSAIQ® for Medical Oncology use, Radiation Oncology use, or the two together. It lets users:

- Assemble electronic patient charts and treatment plans, order diagnostic tests, and prescribe medications.
- Generate and keep medication formulary lists and calculate applicable medication dosages for medical oncology.
- Import, view, annotate, adjust, enhance, manage and archive images.
- Compare radiation treatment plans and evaluate dose coverage.
- Design leaf plans for operation with radiotherapy treatment machines that have multileaf collimators.
- Make sure radiation treatment plans imported from treatment planning systems agree with treatment machine constraints. MOSAIQ® reads actual settings from the treatment machine through the machine communication interface. It compares these settings with predefined values. If a mismatch occurs between the planned values and the actual machine settings, the system warns the user.
- View reference images to setup treatment. MOSAIQ® refers to predefined settings to help treatment machine setup, and communicates patient and machine setup instructions.
- Record actual delivered radiation values in an electronic chart to track treatment.
- Use stereotactic localization to calculate set-up coordinates for treatments.

MOSAIQ® is not intended for use in diagnosis. Medical oncology dose calculation functions are designed for use with patients 18 years or older only.

Prescription Use _X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

MOSAIQ Oncology Information System
Premarket Notification (510(k))
Summary of Safety and Effectiveness

INTRODUCTION

This document summarizes the safety and effectiveness information contained within the MOSAIQ Oncology Information System 510(k). The Summary of Safety and Effectiveness contains no confidential or trade secret information and is intended for full public disclosure and distribution.

PREMARKET NOTIFICATION INFORMATION

1. Product Information:
   - a. Product Trade Name: MOSAIQ
   - b. Release Version Number: Release 2.60
2. Classification Information:
   - a. Classification Name: Medical charged-particle radiation therapy system
   - b. Common/Usual Name: Oncology Information System
   - c. Product Classification: Class II
   - d. Product Code: IYE
   - e. Reference: 21 CFR 892.5050
   - f. Review Panel: Radiology
3. Establishment Information:
   - a. Submitter: IMPAC Medical Systems, Inc.
   - b. Submitter Address: 100 Mathilda Place, 5th Floor, Sunnyvale, CA 94086
   - c. Establishment Number: 2950347
   - d. Contact: Kathryn Stinson, RA Specialist
   - e. Contact Phone: 314-993-0003
   - f. Contact Fax: 314-993-0075

PREDICATE DEVICE INFORMATION

The MOSAIQ Oncology Information System is substantially equivalent to the following devices that the Food and Drug Administration (FDA) has cleared for distribution and are currently being actively marketed in the United States. MOSAIQ is substantially equivalent to these products in intended use and safety and effectiveness.

1. MOSAIQ Oncology Information System
   IMPAC Medical Systems, Inc.
   K123230

2. ERGO++ RTP System
   IMPAC Medical Systems, Inc.
   K080601

MOSAIQ INTENDED USE/INDICATIONS FOR USE

MOSAIQ® is an oncology information system used to manage workflows for treatment planning and delivery. It supports information flow among healthcare facility personnel and can be used wherever radiotherapy and/or chemotherapy are prescribed.

Users can configure MOSAIQ® for Medical Oncology use, Radiation Oncology use, or the two together. It lets users:

- Assemble electronic patient charts and treatment plans, order diagnostic tests, and prescribe medications.
- Generate and keep medication formulary lists and calculate applicable medication dosages for medical oncology.
- Import, view, annotate, adjust, enhance, manage and archive images.
- Compare radiation treatment plans and evaluate dose coverage.
- Design leaf plans for operation with radiotherapy treatment machines that have multileaf collimators.
- Make sure radiation treatment plans imported from treatment planning systems agree with treatment machine constraints. MOSAIQ® reads actual settings from the treatment machine through the machine communication interface. It compares these settings with predefined values. If a mismatch occurs between the planned values and the actual machine settings, the system warns the user.
- View reference images to setup treatment. MOSAIQ® refers to predefined settings to help treatment machine setup, and communicates patient and machine setup instructions.
- Record actual delivered radiation values in an electronic chart to track treatment.
- Use stereotactic localization to calculate set-up coordinates for treatments.

MOSAIQ® is not intended for use in diagnosis. Medical oncology dose calculation functions are designed for use with patients 18 years or older only.

DESCRIPTION OF THE PRODUCT

MOSAIQ is a multi-functional, integrated software suite that forms a comprehensive electronic oncology management system for medical and radiation oncology facilities. For both medical and radiation oncology users, MOSAIQ provides image-enabled electronic patient charting and record management as well as medical transcription and billing functionality. For radiation oncology users, it also includes the ability to import and export radiation treatment plan information, stereotactic localization, treatment plan review, the ability to plan multileaf collimator (MLC) shapes, and verify and record treatment setup and delivery.

This Premarket Notification addresses the addition of the Locate module for Radiation Oncology, which adds stereotactic localization capability to MOSAIQ.

LEVEL OF CONCERN

The FDA guidance document entitled "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," issued May 11, 2005, Table 1, item 4b states, "Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems…."

The record and verify function within MOSAIQ does not directly control the machine that delivers the radiation. However, it does interface with the linear accelerator and is responsible for detecting potential mismatches between planned and actual machine settings and alerting the user. Thus, it is a major level of concern function.

SUMMARY OF CLINICAL TESTING

Clinical trials were not performed as part of the development of this product. Clinical testing on patients is not advantageous in demonstrating substantial equivalence or safety and effectiveness of the device since testing can be performed such that no human subjects are exposed to risk. Bench testing was performed, as described in Section 16.8, using simulated clinical workflows and ad hoc testing where appropriate, with actual patient data. The product was deemed fit for clinical use.

SUMMARY OF NON-CLINICAL TESTING

Verification tests were written and executed to ensure that the system is working as designed. Over 100 test procedures were executed, including tests to verify requirements for new product functionality were met, tests to ensure that risk mitigations function as intended, and regression tests to ensure continued safety and effectiveness of existing functionality. Pass/fail criteria for this testing effort was similar to past testing efforts for

the previous versions of MOSAIQ. MOSAIQ passed testing and was deemed safe and effective for its intended use.

Table 11-1: Substantial Equivalence to Legally Marketed Products	MOSAIQ with Locate (new)	MOSAIQ (Previous) K123230	ERGO++ RTP System K080601
Ability to define leaf plans for use with radiotherapy treatment machines equipped with multileaf collimator	Yes	Yes	Yes
Ability to import, view, annotate, manipulate, enhance, manage and archive images	Yes	Yes	Yes
Allows users to create, view, and edit geometric information associated with treatment field definitions, including the MLC accessory.	Yes	Yes	Yes
Checks radiation treatment plans against treatment machine constraints, provides the capability to notify clinicians of actions that need to take place prior to treatment, displays reference images for setup purposes, and facilitates treatment machine setup according to predefined settings.	Yes	Yes	No
Verification against imported radiation treatment plans	Yes	Yes	No
Recording of actual delivered treatment values	Yes	Yes	No
Record-only interfaces for appropriate treatment machines	Yes	Yes	No
Integrated electronic patient charting functionality	Yes	Yes	No
Administrative functions for practice management (e.g., scheduling, billing)	Yes	Yes	No
Medical oncology management including care plans, calculation of medication dosage & dose delivery tracking	Yes	Yes	No
Security features to enable customer HIPAA compliance	Yes	Yes	Yes
DICOM connectivity with compatible systems	Yes	Yes	Yes
Software runs on Windows operating system	Yes	Yes	No (Linux)
Dose Volume Histogram (DVH) creation and display	Yes	Yes	Yes
Displays DVH Statistics	Yes	Yes	Yes
Comparison of multiple radiation treatment plans	Yes	Yes	Yes
Radiation treatment plan summation and subtraction	Yes	Yes	Yes
Includes ability to evaluate brachytherapy & external beam radiation treatment plans	Yes	Yes	External Beam Only
Isodose & beam display	Yes	Yes	Yes
Supports frame-based stereotactic localization	Yes	No	Yes
Supports frameless stereotactic localization	No	No	No
Support for angiographic images	No	No	Yes
Radiation treatment plan optimization & dose calculation	No	No	Yes
Image contouring functionality	No	No	Yes